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09/447,227	11/22/1999	MARK C. SHULTS	DEXCOM.008DV1	3546

20995 7590 05/08/2007  
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EXAMINER
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NASSER, ROBERT L

ART UNIT	PAPER NUMBER
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3735

NOTIFICATION DATE	DELIVERY MODE
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05/08/2007 ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
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<b>Interview Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/447,227	SHULTS ET AL	
	<b>Examiner</b>	<b>Art Unit</b>	
	Robert L. Nasser	3735	

All participants (applicant, applicant's representative, PTO personnel):

(1) Robert L. Nasser (3) \_\_\_\_\_  
 (2) Laura Johnson (4) \_\_\_\_\_

Date of Interview: 27 April 2007.

Type: a) Telephonic b) Video Conference  
 c) Personal [copy given to: 1) applicant 2) applicant's representative]

Exhibit shown or demonstration conducted: d) Yes e) No.  
 If Yes, brief description: \_\_\_\_\_

Claim(s) discussed: all.

Identification of prior art discussed: all.

Agreement with respect to the claims f) was reached. g) was not reached. h) N/A.

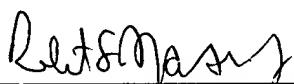
Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: discussed the proposed amendments as to the shape of the device. Applicant pointed out that the shape enhanced the operation of the device and was more than mere design choice. The examiner agreed that the amendments overcame the pending rejection based on Allen, but noted that further consideration was required.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

ROBERT L. NASSER  
 PRIMARY EXAMINER

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

  
 Examiner's signature, if required

## Summary of Record of Interview Requirements

### Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

#### Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

#### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

#### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.



## facsimile transmittal

**To:** Examiner Nasser **Fax:** (571) 273-4731

**From:** Laura Johnson **Date:** 4/23/2007

**Re:** Proposed Amendments **Pages:** 17 including cover sheet

**CC:**

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PRIVILEGED AND CONFIDENTIAL COMMUNICATION This transmission, and any documents attached hereto, may contain confidential and/or legally privileged information. The information is intended only for use by the recipient named above. If you have received this message in error, please notify the sender and delete the electronic message. Any disclosure, copying, distribution, or use of the contents of information received in error is strictly prohibited.

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**PROPOSED AMENDMENTS TO THE CLAIMS  
FOR DISCUSSION PURPOSES ONLY**

**DO NOT ENTER**

1. (Currently amended) A method for evaluating the quality of a calibration of an analyte sensor, the method comprising:

receiving a data stream from an analyte sensor, including one or more sensor data points;

receiving reference data from a reference analyte monitor, including two one or more reference data points;

providing at least two one matched data pairs by matching reference analyte data to substantially time corresponding sensor data;

forming a calibration set including said at least two one matching data pairmatched data pairs;

evaluating the quality of said calibration set using a data association function,

~~creating a conversion function based on said calibration set;~~

~~receiving additional sensor data from the analyte sensor, wherein the step of receiving additional sensor data from the analyte sensor is performed after the step of creating a conversion function;~~

~~converting sensor data into calibrated data using said conversion function~~calibration set;~~~~

providing the calibrated data to a user interface only when the data association is above a predetermined threshold; and

evaluating the quality of said calibration set using a data association function.

2. (Original) The method of claim 1, wherein the step of receiving sensor data comprises receiving a data stream that has been algorithmically smoothed.

3. (Original) The method of claim 1, wherein the step of receiving sensor data comprises algorithmically smoothing said data stream.

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4. (Original) The method of claim 1, wherein the step of receiving sensor data comprises receiving sensor data from a substantially continuous glucose sensor.

5. (Original) The method of claim 1, wherein the step of receiving sensor data comprises receiving sensor data from an implantable glucose sensor.

6. (Original) The method of claim 1, wherein the step of receiving sensor data comprises receiving sensor data from a subcutaneously implantable glucose sensor.

7. (Original) The method of claim 1, wherein the step of receiving reference data comprises receiving reference data from a self-monitoring blood glucose test.

8. (Original) The method of claim 1, wherein the step of receiving reference data comprises downloading reference data via a cabled connection.

9. (Original) The method of claim 1, wherein the step of receiving reference data comprises downloading reference data via a wireless connection.

10. (Original) The method of claim 1, wherein the step of receiving reference data from a reference analyte monitor comprises receiving within a receiver internal communication from a reference analyte monitor integral with said receiver.

11. (Canceled)

12. (Original) The method of claim 1, wherein the step of evaluating the quality of said calibration set based on a data association function comprises performing linear least squares regression.

13. (Original Canceled) The method of claim 12, wherein the step of evaluating the quality of said calibration set based on a data association function comprises setting a threshold of data association.

14. (Original Currently Amended) The method of claim 13, wherein the step of evaluating the quality of said calibration set based on data association comprises performing linear least squares regression and wherein the step of setting a predetermined threshold includes an R-value threshold of 0.79.

15. (Canceled Original) The method of claim 1, further comprising providing an output to a user interface responsive to the quality of said calibration set.

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16. ~~(Canceled Original)~~ The method of claim 15, wherein the step of providing an output includes displaying analyte values to a user dependent upon the quality of said calibration.

17. (Currently amended) The method of claim 15, wherein the step of providing an output ~~calibrated data~~ includes alerting the user dependent upon the quality of said calibration.

18. ~~(Currently Amended Original)~~ The method of claim 15, wherein the step of providing an output ~~calibrated data~~ includes altering the user interface dependent upon the quality of said calibration.

19. ~~(Currently Amended Original)~~ The method of claim 15, wherein the step of providing an output ~~calibrated data~~ includes at least one of providing color-coded information, trend information, directional information, and fail-safe information.

20. (Currently amended) A system for evaluating the quality of a calibration of an analyte sensor, the system comprising:

means for receiving a data stream from an analyte sensor, a plurality of time-spaced sensor data points;

means for receiving reference data from a reference analyte monitor, including ~~two~~ one or more reference data points;

means for providing ~~two~~ one or more matched data pairs by matching reference analyte data to substantially time corresponding sensor data;

means for forming a calibration set including at least ~~two~~ one matched data ~~pair~~ pairs;

means for evaluating the quality of said calibration set based on a data association function;

~~means for creating a conversion function based on said calibration set;~~

~~means for prospectively converting sensor data into calibrated data using said conversion function~~calibration set; and

means for providing calibrated data only when the data association is above a predetermined threshold; and

~~means for evaluating the quality of said calibration set based on a data association function.~~

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21. (Original) The system of claim 20, wherein said means for receiving sensor data comprises means for receiving sensor data that has been algorithmically smoothed.

22. (Original) The system of claim 20, wherein said means for receiving sensor data comprises means for algorithmically smoothing said receiving sensor data.

23. (Original) The system of claim 20, wherein said means for receiving sensor data comprises means for receiving sensor data from substantially continuous glucose sensor.

24. (Original) The system of claim 20, wherein said means for receiving sensor data comprises means for receiving sensor data from an implantable glucose sensor.

25. (Original) The system of claim 20, wherein said means for receiving sensor data comprises means for receiving sensor data from subcutaneously implantable glucose sensor.

26. (Original) The system of claim 20, wherein said means for receiving reference data comprises means for receiving reference data from a self-monitoring blood glucose test.

27. (Original) The system of claim 20, wherein said means for receiving reference data comprises means for downloading reference data via a cabled connection.

28. (Original) The system of claim 20, wherein said means for receiving reference data comprises means for downloading reference data via a wireless connection.

29. (Original) The system of claim 20, wherein said means for receiving reference data from a reference analyte monitor comprises means for receiving within a receiver internal communication from a reference analyte monitor integral with said receiver.

30. (Original) The system of claim 20, wherein said means for evaluating the quality of said calibration set comprises means for performing one of linear regression, non-linear regression, rank correlation, least mean square fit, mean absolute deviation, and mean absolute relative difference.

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31. (Original) The system of claim 20, wherein said means for evaluating the quality of said calibration set comprises means for performing linear least squares regression.

32. (~~Original Canceled~~) ~~The system of claim 31, wherein said means for evaluating the quality of said calibration set comprises means for setting a threshold of data association.~~

33. (~~Original~~ Currently Amended) The system of claim 3220, wherein said means for evaluating the quality of said calibration set comprises means for performing linear least squares regression and wherein said ~~means for setting a predetermined threshold~~ ~~includes an~~ ~~comprises~~ an R-value threshold of 0.71.

34. (~~Canceled Original~~) ~~The system of claim 20, further comprising means for providing an output to a user interface responsive to the quality of said calibration set.~~

35. (~~Canceled Original~~) ~~The system of claim 34, wherein said means for providing an output includes means for displaying analyte values to a user dependent upon the quality of said calibration.~~

36. (Currently amended) The system of claim 3420, wherein said means for providing ~~an output~~ ~~calibrated data~~ includes means for alerting the user dependent upon the quality of said calibration.

37. (Currently Amended ~~Original~~) The system of claim 3420, wherein said means for providing ~~an output~~ ~~calibrated data~~ includes means for altering the user interface dependent upon the quality of said calibration.

38. (Currently Amended ~~Original~~) The system of claim 3420, wherein said means for providing ~~an output~~ ~~calibrated data~~ includes at least one of providing color-coded information, trend information, directional information, and fail-safe information.

39. (Currently amended) A computer system for evaluating the quality of a calibration of an analyte sensor, the computer system comprising:

a sensor data receiving module that receives a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor;

a reference data receiving module that receives reference data from a reference analyte monitor, including ~~two~~ one or more reference data points;

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a data matching module that forms two one or more matched data pairs by matching reference data to substantially time corresponding sensor data;

a calibration set module that forms a calibration set including at least two one matched data pairs;

a quality evaluation module that evaluates the quality of said calibration set based on a data association function

~~a conversion function module that creates a conversion function using said calibration set;~~

a sensor data transformation module that ~~prospectively~~ converts sensor data into calibrated data using said ~~conversion function~~ calibration set;

an interface control module that displays said calibrated data only when the data association is above a predetermined threshold; and,

~~a quality evaluation module that evaluates the quality of said calibration set based on a data association function.~~

40. (Original) The computer system of claim 39, wherein said sensor data receiving module receives sensor data that has been algorithmically smoothed.

41. (Original) The computer system of claim 39, further comprising a data smoothing module that algorithmically smoothes sensor data received from said sensor data receiving module.

42. (Original) The computer system of claim 39, wherein said sensor data receiving module is adapted to receive sensor data from substantially continuous glucose sensor.

43. (Original) The computer system of claim 39, wherein said sensor data receiving module is adapted to receive sensor data from an implantable glucose sensor.

44. (Original) The computer system of claim 39, wherein said sensor data receiving module is adapted to receive sensor data from subcutaneously implantable glucose sensor.

45. (Original) The computer system of claim 39, wherein said reference data receiving module is adapted to receive reference data from a self-monitoring blood glucose test.

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46. (Original) The computer system of claim 39, wherein said reference data receiving module is adapted to download reference data via a cabled connection.

47. (Original) The computer system of claim 39, wherein said reference data receiving module is adapted to download reference data via a wireless connection.

48. (Original) The computer system of claim 39, wherein said reference data receiving module is adapted to receive reference data from a reference analyte monitor integral with said receiver.

49. (Canceled)

50. (Original) The computer system of claim 39, wherein said quality evaluation module performs linear least squares regression.

51. (Original Canceled) The computer system of claim 50, wherein said quality evaluation module sets a threshold for said data association function.

52. (Original Currently Amended) The computer system of claim 51, wherein said quality evaluation module performs linear least squares regression and wherein the predetermined threshold of said data association function includes an R-value threshold of at least 0.79.

53. (Canceled Original) The computer system of claim 39, further comprising an interface control module that controls the user interface based on the quality of said calibration set.

54. (Canceled Original) The computer system of claim 53, wherein said interface control module displays analyte values to a user dependent upon the quality of said calibration set.

55. (Currently Amended Original) The computer system of claim 53, wherein said interface control module alerts the user based upon the quality of said calibration set.

56. (Currently Amended Original) The computer system of claim 53, wherein said interface control module alters the user interface based upon the quality of said calibration set.

57. (Currently Amended Original) The computer system of claim 53, wherein said interface control module provides at least one of color-coded information, trend information, directional information, and fail-safe information.

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58. (Currently amended) A method for evaluating the quality of a calibration of an analyte sensor, the method comprising:

receiving a data stream from an analyte sensor, including one or more sensor data points;

receiving reference data from a reference analyte monitor, including two one or more reference data points;

providing at least two one matched data pairs by matching reference analyte data to substantially time corresponding sensor data;

forming a calibration set including comprising no more than said at least two matching matched data pairs for a single day; and

~~creating a conversion function based on said calibration set;~~

~~prospective~~ converting additional sensor data into calibrated data using said conversion function; and

~~evaluating the~~ a quality of said calibration set based on a data association function, selected from the group consisting of linear regression, non linear regression, rank correlation, least mean square fit, mean absolute deviation, and mean absolute relative difference.

59. (Currently amended) A method for evaluating the quality of a calibration of an analyte sensor, the method comprising:

receiving analyte sensor data from an analyte sensor;

receiving reference data from a reference analyte monitor;

providing at least two one matched data pairs by matching reference analyte data to substantially time corresponding sensor data;

~~creating forming a conversion function calibration set based on comprising~~ said at least two one matched data pairs;

evaluating a quality of said calibration set; and

modifying said calibration set when the quality of said calibration is below a predetermined threshold, converting sensor data into substantially real-time analyte values using said conversion function as sensor data is continuously or intermittently received from the sensor; and

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~~providing an output to a user interface responsive to the data association of said at least two matched data pairs.~~

60. (Currently amended) A computer system for evaluating the quality of a calibration of an analyte sensor, the computer system comprising:

a sensor data module ~~that configured to~~ receives a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor;

a reference input module ~~that configured to~~ receives reference data from a reference analyte monitor, including ~~two~~one or more reference data points;

a processor module ~~that configured to~~ forms ~~two~~one or more matched data pairs by matching reference data to substantially time corresponding sensor data, ~~wherein the processor module is further configured to and subsequently~~ forms a calibration set including ~~said~~no more than two or more matched data pairs for a single day; and

a conversion function module that creates a conversion function using ~~said calibration set~~;

a sensor data transformation module that prospectively converts additional sensor data into calibrated data using ~~said conversion function~~; and

a quality evaluation module ~~that configured to~~ evaluates the quality of ~~said calibration set based on a data association~~ ~~function~~ ~~selected from the group consisting of linear regression, non linear regression, rank correlation, least mean square fit, mean absolute deviation, and mean absolute relative difference.~~

61. (Currently amended) A computer system for evaluating the quality of a calibration of an analyte sensor, the computer system comprising:

a sensor data module ~~that configured to~~ receives analyte sensor data from a substantially continuous analyte sensor;

a reference input module ~~that configured to~~ receives reference data from a reference analyte monitor;

a processor module ~~that configured to~~ forms a calibration set comprising ~~two~~one or more matched data pairs by matching reference data to substantially

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~~time corresponding sensor data—a conversion function module that creates a conversion function using said two or more matched data pairs; and~~

~~a quality evaluation module configured to evaluate the quality of said calibration set, wherein the processor module is configured to modify the calibration set when the quality of said calibration set is below a predetermined threshold; a sensor data transformation module that converts sensor data into substantially real-time analyte values using said conversion function as sensor data is continuously or intermittently received from the sensor; and~~

~~a fail-safe module that controls the user interface based on the data association of said two or more matched data pairs.~~

62. (Currently amended) A method for evaluating the quality of a calibration of a glucose sensor, the method comprising:

receiving sensor data from a glucose sensor, including one or more sensor data points;

receiving reference data from a reference glucose monitor, including one or more reference data points;

providing one or more matched data pairs by ~~matched~~ matching reference glucose data to substantially time corresponding sensor glucose data;

forming a calibration set including at least one matched data pair

evaluating the quality of said calibration set based on data association; and

~~converting~~ processing real-time sensor data into calibrated data responsive to the quality of said calibration set above a predetermined threshold.

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63 (New) The method of claim 59, wherein the step of evaluating a quality of said calibration set comprises evaluating the association of the calibration set data using statistical analysis.

64. (New) The method of claim 59, wherein the step of evaluating a quality of said calibration set comprises evaluating the calibration set for clinical acceptability.

65 (New) The system of claim 61, wherein the quality evaluation module is configured to evaluate the association of the calibration set data using statistical analysis.

66. (New) The method of claim 61, wherein the quality evaluation module is configured to evaluate the calibration set for clinical acceptability.

**DRAFT CLAIM AMENDMENT**  
**FOR DISCUSSION ONLY**  
**NOT TO BE ENTERED INTO FILE**  
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1-32. (Canceled)

33. (Previously presented) A method according to claim 34, wherein said device is wholly implanted subcutaneously in said host.

34. (Currently amended) A method of measuring glucose in a biological fluid, comprising the steps of:

- a) providing a host;
- b) providing an implantable device comprising a sensor capable of continuous glucose sensing, ~~said sensor having a protruding interface tip, said implantable device comprising a housing, a sensing membrane, and a first domain, and a second domain, wherein said first domain is positioned more distal to said housing than said second domain; wherein said first domain supports tissue ingrowth comprises an angiogenic layer; wherein said sensing membrane is positioned more proximal to said housing than said second first domain; wherein said sensing membrane comprises an enzyme; wherein said housing comprises a first portion and a second portion, wherein a curvature of the second portion is greater than a curvature of the first portion; wherein said second domain is situated between said first domain and said sensing membrane; wherein said first domain is disposed on located over at least a portion of said interface tip second portion; and wherein said second domain is impermeable to macrophages;~~
- c) implanting said device subcutaneously into a tissue of said host so as to elicit a foreign body capsule as a result of the response of said host to the introduction of said implantable device, ~~said sensor interface tip communicating with the tissue of said host such that said tip is anchored by tissue ingrowth in said foreign body capsule.~~

35-37. (Canceled)

38. (Currently amended) A method of monitoring glucose levels, comprising:

- a) providing i) a host, and ii) a device comprising a housing and a sensor capable of continuous glucose sensing, ~~wherein said sensor comprising a housing comprises a convexly curved portion over which sensor interface tip comprising a sensing membrane and, a first domain are located, and a second domain; wherein said device comprises a body and wherein said sensor interface tip protrudes beyond a plane of the body to assist in formation of vasculature; wherein said first domain is positioned~~

**DRAFT CLAIM AMENDMENT**  
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more distal to said housing than said second domain; wherein said first domain supports tissue ingrowth comprises a vascularization promotion layer; wherein said sensing membrane is positioned more proximal to said housing than said second first domain; wherein said sensing membrane comprising an enzyme; wherein said second domain is situated between said first domain and said sensing membrane; and wherein said second domain is impermeable to macrophages; and

b) wholly-implanting said device subcutaneously in said host under conditions such that said device provides continuous glucose sensing, wherein said device is anchored in said host by tissue ingrowth.

39-40. (Canceled)

41. (Previously presented) A method according to claim 38, wherein said implant is sized and configured for being wholly implanted subcutaneously.

42. (Previously presented) A method according to claim 41, further including the step of transmitting data from said wholly implanted device telemetrically.

43-47. (Canceled)

48. (Previously presented) The method of claim 34, wherein said sensing membrane comprises an enzyme comprises glucose oxidase.

49. (Previously presented) The method of claim 38, wherein said sensing membrane comprises an enzyme comprises glucose oxidase.

50-53. (Canceled)

54. (Previously presented) The method of claim 34, wherein said implantable device further comprises an electrolyte phase, wherein said electrolyte phase is situated between said sensing membrane and said sensor.

55. (Previously presented) The method of claim 38, wherein said device further comprises an electrolyte phase, wherein said electrolyte phase is situated between said sensing membrane and said sensor.

56. (Previously presented) The method of claim 38, further comprising implanting said device in said host under conditions such that said device measures said glucose accurately for a period of time exceeding 90 days.

**DRAFT CLAIM AMENDMENT**  
**FOR DISCUSSION ONLY**  
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57. (Previously presented) The method of claim 56, wherein said device measures said glucose accurately for a period exceeding 150 days.

58. (Previously presented) The method of claim 56, wherein said device measures said glucose accurately for a period exceeding 360 days.

59. (Previously presented) The method of claim 38, further comprising explanting said device after 90 days.

60. (Previously presented) The method of claim 59, wherein said device is explanted after 150 days.

61. (Previously presented) The method of claim 59, wherein said device is explanted after 360 days.

62. (Previously presented) The method of claim 38, wherein said first domain stabilizes over a time period to produce long-term level reflecting adequate microcirculatory delivery of glucose and oxygen to said sensor.

63. (Previously presented) The method of claim 38, wherein said first domain is formed from a material selected from the group consisting of polytetrafluoroethylene, hydrophilic polyvinylidene fluoride, mixed cellulose esters, polyvinyl chloride, polyethylene, polypropylene, Teflon, cellulose acetate, cellulose nitrate, polycarbonate, polyester, nylon, polysulphone, polymethacrylate, mixed esters of cellulose polyvinylidene difluoride, silicone, and polyacrylonitrile.

64. (Previously presented) The method of claim 38, wherein said vascular promotion layer comprises a material that has a characteristic of stimulating growth of new vascular structures by said host close to said device.

65. (Previously presented) The method of claim 38, wherein said sensor senses glucose using an enzymatic mechanism.

66. (Previously presented) The method of claim 38, wherein said sensor senses glucose using a non-enzymatic mechanism.

67. (Previously presented) The method of claim 38, wherein said sensor senses glucose using a resonance mechanism.

68. (Previously presented) The method of claim 38, wherein said sensor senses glucose using an acoustic wave mechanism.

**DRAFT CLAIM AMENDMENT**  
**FOR DISCUSSION ONLY**  
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69. (Previously presented) The method of claim 38, wherein said sensor senses glucose using an optical mechanism.

70. (Previously presented) The method of claim 34, further comprising implanting said device in said host under conditions such that said device measures said glucose accurately for a period of time exceeding 90 days.

71. (Previously presented) The method of claim 70, wherein said device measures said glucose accurately for a period exceeding 150 days.

72. (Previously presented) The method of claim 70, wherein said device measures said glucose accurately for a period exceeding 360 days.

73. (Previously presented) The method of claim 34, further comprising explanting said device after 90 days.

74. (Previously presented) The method of claim 73, wherein said device is explanted after 150 days.

75. (Previously presented) The method of claim 73, wherein said device is explanted after 360 days.

76. (Previously presented) The method of claim 34, wherein said first domain stabilizes over a time period to produce long-term level reflecting adequate microcirculatory delivery of glucose and oxygen to said sensor.

77. (Previously presented) The method of claim 34, wherein said first domain is formed from a material selected from the group consisting of polytetrafluoroethylene, hydrophilic polyvinylidene fluoride, mixed cellulose esters, polyvinyl chloride, polyethylene, Teflon, cellulose acetate, cellulose nitrate, polycarbonate, polyester, nylon, polypropylene, polymethacrylate, polysulfone, mixed esters of cellulose polyvinylidene difluoride, silicone, and polyacrylonitrile.

78. (Previously presented) The method of claim 34, wherein said first domain comprises a material that has a characteristic of stimulating growth of new vascular structures by said host close to said device.

79. (Previously presented) The method of claim 34, wherein said sensor senses glucose using an enzymatic mechanism.

**DRAFT CLAIM AMENDMENT**  
**FOR DISCUSSION ONLY**  
**NOT TO BE ENTERED INTO FILE**  
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80. (Previously presented) The method of claim 34, wherein said sensor senses glucose using a non-enzymatic mechanism.

81. (Previously presented) The method of claim 34, wherein said sensor senses glucose using a resonance mechanism.

82. (Previously presented) The method of claim 34, wherein said sensor senses glucose using an acoustic wave mechanism.

83 (Previously presented) The method of claim 34, wherein said sensor senses glucose using an optical mechanism.

84-87. (Canceled)

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